

comprising:

an injection device having a hollow injection needle with an opening at a tip and seed-depositing means for having a radioactive seed pushed therethrough to be deposited in a patient's body through said opening proximal to said tip;

seed-position detecting means for determining position, with reference to a space-fixed coordinate system, of a seed deposited in the patient's body by said injection device;

real-time seed-position determining means for determining position of said deposited seed in real time with reference to a body-fixed coordinate system which is affixed to said patient's body; and

dose calculating means for calculating in real time a radiation dose distribution within a selected volume specified with respect to said body-fixed coordinate system due to seeds which have been deposited by said injection device.

#### R E M A R K S

Claims 1-22 currently remain in the application. Claim 1 is herein amended.

Claims 1-11 were rejected under 35 U.S.C. 101 because the claimed invention is alleged to be directed to non-statutory subject matter. The Examiner states that claims 1-11 pertain to "applying medical devices to the human body". However, it should be clear that claims 1-11 are product claims, addressed to an "apparatus for brachytherapy" to be used with whichever part of a body of a patient that needs the treatment. In view of the many patents that have been issued on therapy devices such as radiation therapy apparatus, the Examiner is requested to clarify the reason for the rejection in the Official Letter such that applicant can amend the claims section in order to overcome the rejection. In order to expedite the prosecution, however, applicant hereby amends independent claim 1 to make certain that the subject apparatus is primarily for use with a human body.

Claims 1-22 were rejected under 35 U.S.C. 103 over Burdette in view of Franck. The Examiner's opinion is that Burdette discloses every inventive element in the rejected claims except for the use of a body-fixed coordinate system, a reference point detecting means and a referencing means but that Franck discloses these inventive points missed by Burdette. When a claim is rejected as being obvious over one reference in view of another reference, it

frequently becomes an issue whether it would have been obvious to combine the teachings in these two different references. In the instant rejection, the Examiner justifies the combination by observing that both references relate to a stereotactic surgical procedure. A stereotactic surgical procedure, however, can be performed on different parts of a body, and it goes without saying that the human body includes many parts which are so different in character that different procedures must be employed by doctors trained in different branches of medical science. For example, a dental surgeon would not even dream of performing appendectomy by using his/her instruments. Burdette relates to the treatment of the prostate, while Franck relates to the use of "bone anchors" (lines 4, 13 and 20 of Abstract, and elsewhere) on the skull and the spine. Would a surgeon who carries out a prostate treatment routinely carry out a brain surgery? It should be clear that bone anchors are impractical, if not totally inappropriate, in the treatment of a prostate.

As the Examiner correctly stated, furthermore, Franck discloses a body-mounted sensing system such as a number of cameras attached to the bone anchors (lines 11-13 of Abstract), while Burdette is totally silent of any advantages to be gained by such a setup. Moreover, Franck does not relate to placing of any radioactive seeds or to the use of a hollow needle. What is inserted into the patient's body is variously referred to as the "instrument" or the "electrode". This additionally tells that Franck and Burdette relate to different kinds of medical treatment.

In other words, The approach to the use of a visualization system is totally different between Burdette and Franck. Under such circumstances, it would be unreasonable to expect either Burdette or Franck to borrow any idea regarding the visualization scheme from the other. In summary, the two references relate to treatments of totally different parts of the human body, although they both utilize a visualization system each for its own method of treating a different part of the human body requiring attention of a different kind, and hence Burdette would not have been motivated to borrow any teaching from Franck.

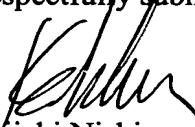
The Examiner wrote "See whole document" twice in the Official Letter (page 3, lines 6 and 13). It is indeed a significant statement, which seems to indicate that the pertinence of one to the other would not be apparent unless these two rather lengthy documents were carefully read in their entirety. In view thereof, would Burdette, for example, have been

tempted to read Franck's document in its entirety, knowing that Franck did not relate to the treatment of a prostate or the like, but to a brain surgery? The Examiner is requested to reconsider his rejection and to come to agree that there is more of a reason to believe that Burdette would not have been motivated to read the whole document of Franck.

The present invention is further distinguishable from either of the cited references in that the needle 11 itself can be moved such that its tip (where the opening 13 is) can be correctly at a target position because the control system 30 is capable of determining the position of the opening 13 (page 5, lines 10-12). By contrast, Burdette does not operate the needle 19 directly but by way of the template 25. As is the subject matter of another patent application already filed by the inventor herein, the needle is easily deflected or bent when it encounters a hard part of the tissue. In other words, the user of Burdette's apparatus cannot be certain of the exact position of the tip of the needle which is being operated by the template. This aspect of the invention has not been introduced into the claims section, nor is it being introduced in the instant Amendment, because it is believed that the argument presented above alone is sufficient to convince the Examiner to withdraw the rejection.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Respectfully submitted,



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January 31, 2002  
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claim 1 has been amended as follows:

1. (Amended) An apparatus for use with a human body for brachytherapy comprising:

an injection device having a hollow injection needle with an opening at a tip and seed-depositing means for having a radioactive seed pushed therethrough to be deposited in a patient's body through said opening proximal to said tip;

seed-position detecting means for determining position, with reference to a space-fixed coordinate system, of a seed deposited in the patient's body by said injection device;

real-time seed-position determining means for determining position of said deposited seed in real time with reference to a body-fixed coordinate system which is affixed to said patient's body; and

dose calculating means for calculating in real time a radiation dose distribution within a selected volume specified with respect to said body-fixed coordinate system due to seeds which have been deposited by said injection device.